

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

IN RE: MESH PRODUCTS LITIGATION

CASE NO. 3:09-hcd-00001

THIS DOCUMENT RELATES TO CIVIL ACTION NO.

MARY WATSON,

Plaintiff,

v.

C. R. BARD, INC., and
COVIDIEN INC. d/b/a SOFRADIM
PRODUCTION,

Defendants.

Civil Action No. 3:09-cv-1555

C. R. BARD, INC.'S ANSWER AND DEFENSES

Defendant C. R. Bard, Inc. (hereinafter "Bard") hereby files its Answer and Defenses to the plaintiff's Complaint as follows:

FIRST DEFENSE

The plaintiff's Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

SECOND DEFENSE BY WAY OF FURTHER ANSWER

Bard responds to the specifically numbered allegations of the plaintiff's Complaint as follows:

PARTIES, JURISDICTION AND VENUE

1. After reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Complaint.

2. In response to Paragraph 2 of the Complaint, Bard admits that it is a New Jersey corporation with its principal place of business at 730 Central Avenue, Murray Hill, New Jersey 07974. The remaining allegations of Paragraph 2 are denied.

3. In response to Paragraph 3 of the Complaint, Bard admits that Covidien Inc. d/b/a Sofradim Production (hereinafter "Covidien") is a Delaware Corporation with its principal place of business at 15 Hampshire Street, Mansfield, Massachusetts 02048. The remaining allegations in Paragraph 3 are denied.

4. After reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of the allegations contained in Paragraph 4 of the Complaint, and, thus, Bard demands strict proof thereof.

5. Bard denies the allegations contained in Paragraph 5 of the Complaint.

FACTUAL BACKGROUND

6. Bard admits that it has generally been engaged in the business of designing, manufacturing, and selling certain medical devices and admits that from time to time in the past it has sold, designed, and distributed surgical mesh support products under the name Avaulta* in various states, including West Virginia. Except as specifically admitted herein, Bard denies the allegations contained in Paragraph 6 of the Complaint.

7. Bard admits that Covidien has generally been engaged in the business of designing, manufacturing, and selling certain medical devices and admits that from time to time in the past it has designed and manufactured surgical mesh support products sold by Bard under the name Avaulta* in various states, including West Virginia. Except as specifically admitted herein, Bard denies the allegations contained in Paragraph 7 of the Complaint.

8. After reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of the allegations contained in Paragraph 8 of the Complaint, and, thus, Bard demands strict proof thereof.

9. After reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of the allegations contained in Paragraph 9 of the Complaint, and, thus, Bard demands strict proof thereof.

10. Bard denies the allegations contained in Paragraph 10 of the Complaint.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

11. Bard hereby incorporates by reference its responses to Paragraphs 1-10 of the Complaint.

12. Bard denies the allegations contained in Paragraph 12 of the Complaint.

13. Bard denies the allegations contained in Paragraph 13 of the Complaint.

14. Bard denies the allegations contained in Paragraph 14 of the Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

15. Bard hereby incorporates by reference its responses to Paragraphs 1-10 of the Complaint.

16. Bard denies the allegations contained in Paragraph 16 of the Complaint.

17. Bard denies the allegations contained in Paragraph 17 of the Complaint.

18. Bard denies the allegations contained in Paragraph 18 of the Complaint.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

19. Bard hereby incorporates by reference its responses to Paragraphs 1-10 of the Complaint.

20. Bard denies the allegations contained in Paragraph 20 of the Complaint.

21. Bard denies the allegations contained in Paragraph 21 of the Complaint.

22. Bard denies the allegations contained in Paragraph 22 of the Complaint.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

23. Bard hereby incorporates by reference its responses to Paragraphs 1-10 of the Complaint.

24. Bard denies the allegations contained in Paragraph 24 of the Complaint.

25. Bard denies the allegations contained in Paragraph 25 of the Complaint.

26. Bard denies the allegations contained in Paragraph 26 of the Complaint.

COUNT V: BREACH OF EXPRESS WARRANTY

27. Bard hereby incorporates by reference its responses to Paragraphs 1-10 of the Complaint.

28. Bard denies the allegations contained in Paragraph 28 of the Complaint.

29. Bard denies the allegations contained in Paragraph 29 of the Complaint.

30. Bard denies the allegations contained in Paragraph 30 of the Complaint.

31. Bard denies the allegations contained in Paragraph 31 of the Complaint.

32. Bard denies the allegations contained in Paragraph 32 of the Complaint.

33. Bard denies the allegations contained in Paragraph 33 of the Complaint.

COUNT VI: BREACH OF IMPLIED WARRANTY

34. Bard hereby incorporates by reference its responses to Paragraphs 1-10 of the Complaint.

35. Bard denies the allegations contained in Paragraph 35 of the Complaint.

36. Bard denies the allegations contained in Paragraph 36 of the Complaint.

- 37. Bard denies the allegations contained in Paragraph 37 of the Complaint.
- 38. Bard denies the allegations contained in Paragraph 38 of the Complaint.
- 39. Bard denies the allegations contained in Paragraph 39 of the Complaint.
- 40. Bard denies the allegations contained in Paragraph 40 of the Complaint.

COUNT VIII: PUNITIVE DAMAGES

- 41. Bard hereby incorporates by reference its responses to Paragraphs 1-10 of the Complaint.
- 42. Bard denies the allegations contained in Paragraph 42 of the Complaint.
- 43. Bard denies the allegations contained in Paragraph 43 of the Complaint.
- 44. Further, responding to the unnumbered Paragraph, including sub-parts, following Paragraph 43 of the Complaint entitled “AD DAMNUM,” Bard denies the allegations contained in such Paragraph. Bard further denies each and every allegation not specifically admitted herein. Bard denies that the plaintiff is entitled to any relief requested in the Complaint.

THIRD DEFENSE

The sole proximate cause of the plaintiff’s damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Bard was and is in no way liable.

FOURTH DEFENSE

If the plaintiff has been damaged, which Bard denies, any recovery by the plaintiff is barred to the extent Plaintiff Mary Watson voluntarily exposed herself to a known risk and/or failed to mitigate her alleged damages. To the extent the plaintiff has failed to mitigate her

alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

FIFTH DEFENSE

The plaintiff failed to exercise ordinary care for her own safety such that the plaintiff is not entitled to recover.

SIXTH DEFENSE

The injuries and damages allegedly sustained by the plaintiff may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in the plaintiff over which Bard had no control.

SEVENTH DEFENSE

The plaintiff's causes of action may be barred by the applicable statute of limitations and/or statute of repose.

EIGHTH DEFENSE

The plaintiff's claims are barred, in whole or in part, by the doctrines of laches, waiver, and/or estoppel.

NINTH DEFENSE

There was no defect in the products at issue with the result that the plaintiff is not entitled to recover against Bard in this cause.

TENTH DEFENSE

There was no causal connection between any alleged defect in the products at issue and plaintiff's alleged damages with the result that plaintiff is not entitled to recover against Bard in this cause.

ELEVENTH DEFENSE

If the plaintiff has been damaged, which Bard denies, such damages were caused by the negligence or fault of the plaintiff.

TWELFTH DEFENSE

If the plaintiff has been damaged, which Bard denies, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Bard is not legally responsible.

THIRTEENTH DEFENSE

If the plaintiff suffered any damages or injuries, which are denied, Bard states that the plaintiff was guilty of comparative negligence and therefore any recovery should be reduced proportionately.

FOURTEENTH DEFENSE

In the further alternative, and only in the event that it is determined that the plaintiff is entitled to recover against Bard, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to the plaintiff, any other defendants, third party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom the plaintiff has settled or may settle in the future.

FIFTEENTH DEFENSE

If the plaintiff has been damaged, which Bard denies, the negligence or fault of the plaintiff constitutes the sole, intervening, and superseding cause of the plaintiff's alleged damages.

SIXTEENTH DEFENSE

If the plaintiff has been damaged, which Bard denies, the negligence or fault of persons and/or entities for whose conduct Bard is not legally responsible constitutes the sole, intervening, and superseding cause of the plaintiff's alleged damages.

SEVENTEENTH DEFENSE

If the plaintiff has been damaged, which Bard denies, the actions of persons or entities for whose conduct Bard is not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the product and other independent causes, constitute an intervening and superseding cause of the plaintiff's alleged damages.

EIGHTEENTH DEFENSE

If the plaintiff has been damaged, which Bard denies, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Bard is not legally responsible.

NINETEENTH DEFENSE

If the plaintiff has been damaged, which Bard denies, such damages were caused by abuse, misuse, user error and/or modification of the product at issue for which Bard was and is in no way liable.

TWENTIETH DEFENSE

Bard made no warranties of any kind, express or implied, including any alleged implied warranty of merchantability or implied warranty of fitness for a particular purpose, or any representations of any nature whatsoever to the plaintiff. To the extent applicable, the plaintiff's breach of warranty claims are barred by a lack of privity between the plaintiff and

Bard. To the extent the plaintiff makes warranty claims, whether express or implied, the claims are barred or limited by any and all express conditions or disclaimers, by the plaintiff's lack of reliance on any such warranties, and by waiver.

TWENTY-FIRST DEFENSE

The plaintiff's claims for breach of implied warranty must fail because the product was not used for its ordinary purpose.

TWENTY-SECOND DEFENSE

The plaintiff's claim for breach of warranty is barred because the plaintiff did not first give notice of any alleged defect of the product to Bard.

TWENTY-THIRD DEFENSE

Bard neither had nor breached any alleged duty to warn with respect to the product, with the result that the plaintiff is not entitled to recover in this cause.

TWENTY-FOURTH DEFENSE

The plaintiff's failure to warn claims are barred by virtue of the intervention of the learned intermediary or intermediaries to whom Bard discharged its duties to warn.

TWENTY-FIFTH DEFENSE

The conduct of Bard and the subject product at all times conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statute and regulations. Accordingly, the plaintiff's claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

TWENTY-SIXTH DEFENSE

The plaintiff's alleged damages resulted from independent, unforeseeable, superseding, and/or intervening causes unrelated to any conduct of Bard.

TWENTY-SEVENTH DEFENSE

If the plaintiff recovers from Bard, it is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause the plaintiff's alleged damages.

TWENTY-EIGHTH DEFENSE

The plaintiff's claims are or may be barred, in whole or in part, to the extent that the plaintiff has released, settled with, entered into an accord and satisfaction, or otherwise compromised her claims. Bard is entitled to a set-off for the entire amount of proceeds the plaintiff has or may recover from all other sources.

TWENTY-NINTH DEFENSE

Should Bard be held liable to the plaintiff, which liability is specifically denied, Bard would be entitled to a setoff for the total of all amounts paid to the plaintiff from all collateral sources.

THIRTIETH DEFENSE

Bard asserts any and all defenses, claims, credits, offsets, or remedies provided by the Restatement (Third) of Torts and reserves the right to amend its Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

THIRTY-FIRST DEFENSE

The products at issue are neither defective nor unreasonably dangerous because they are medical devices falling within what is commonly known as Comment (j), Restatement (Second) of Torts § 402A, and comparable provisions of the Restatement (Third) of Torts (Products Liability), in that the products at issue are, at all times material to the plaintiff's Complaint, reasonably safe and reasonably fit for its intended use, and the warnings and instructions accompanying the product at the time of the occurrence or injuries alleged by the plaintiff was legally adequate.

THIRTY-SECOND DEFENSE

The plaintiff's claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the product at issue conformed with the generally recognized, reasonably available, and reliable state of knowledge when the product was manufactured and marketed.

THIRTY-THIRD DEFENSE

The plaintiff's claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the product at issue conformed with industry custom/usage standards and/or legislative/administrative/regulatory standards.

THIRTY-FOURTH DEFENSE

The design complained of in the plaintiff's Complaint, the alleged defects of the product, and/or any alternative design claimed by the plaintiff was not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the product at issue was designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

THIRTY-FIFTH DEFENSE

Bard specifically pleads all affirmative defenses under the Uniform Commercial Code (“UCC”) now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

THIRTY-SIXTH DEFENSE

No act or omission of Bard was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

THIRTY-SEVENTH DEFENSE

To the extent the plaintiff asserts a demand for punitive damages, Bard specifically incorporates by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

THIRTY-EIGHTH DEFENSE

To the extent that the plaintiff asserts a claim for punitive damages, that claim is in contravention of the rights of Bard under the following constitutional provisions:

1. Plaintiff’s claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

- (a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive

damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the “beyond a reasonable doubt” burden of proof required in criminal cases;

- (b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;
- (c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendants, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;
- (f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause

of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

- (g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;
- (h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and
- (i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

2. The plaintiff's claims for punitive or exemplary damages violate and are, therefore, barred by the provision of the Constitution of the State of West Virginia, including but not limited to Article III, Sections 4, 5, 6 and 10, on grounds including the following:

- (a) it is a violation of the Due Process and Equal Protection Clauses to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- (b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing;
- (c) the procedures to which punitive damages are awarded fail to provide a limit on the amount of the award against defendant;
- (d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages;

- (e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts;
- (f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct;
- (g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines;
- (h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and
- (i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

THIRTY-NINTH DEFENSE

Bard intends to rely upon any additional affirmative defenses that become available during the course of investigation and/or discovery and reserves the right to amend its Answer to assert these defenses.

REQUEST FOR JURY TRIAL

Bard seeks a trial by jury on all issues so triable.

WHEREFORE, Bard states that the plaintiff is not entitled to the relief demanded in the Complaint, and this Defendant, having fully answered, prays that this action against it be dismissed and that it be awarded its costs in defending this action and that it be granted such other and further relief as the Court deems just and appropriate.

C. R. BARD, INC.

By: /s/ Marc E. Williams
Of Counsel

Marc E. Williams, Esq. (WVSN 4062)
Melissa Foster Bird, Esq. (WVSN 6588)
NELSON MULLINS RILEY & SCARBOROUGH LLP
1035 Third Avenue, Suite 300
Huntington, West Virginia 25701
(800) 237-2000 – Telephone

COUNSEL FOR C. R. BARD, INC.

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COVIDIEN INC. d/b/a SOFRADIM
PRODUCTION,

Defendants.

CERTIFICATE OF SERVICE

I hereby certify that I have served the within and foregoing **C. R. Bard, Inc.'s Answer and Defenses** upon the following individuals via electronic filing with the Court's CM/ECF system, on the 11th day of January 2010:

Derek W. Marsteller
Marsteller Law Offices
622 7th Street
P.O. Box 1506
Huntington, West Virginia 25701-1506

Gary B. Blasingame
Henry G. Garrard, III
Blasingame, Burch, Garrard & Ashley, PC
440 College Ave.
Athens, GA 30601

C. R. BARD, INC.

By: /s/ Marc E. Williams
Of Counsel

Marc E. Williams, Esq. (WVSN 4062)
Melissa Foster Bird, Esq. (WVSN 6588)
NELSON MULLINS RILEY & SCARBOROUGH LLP
1035 Third Avenue, Suite 300
Huntington, West Virginia 25701
(800) 237-2000 – Telephone

COUNSEL FOR C. R. BARD, INC.